

REMARKS

Claims 1-7 are pending. Claims 1 and 7 are amended.

Claims 1 and 7 are amended to recite, *inter alia*, “wherein the ethanolate is less hygroscopic than azithromycin monohydrate.” Literal support for the amendments to the claims can be found at, for example, page 2, lines 11-13, of the specification. Page 2, lines 11-13, of the specification discloses “a new ethanolate of azithromycin that is less hygroscopic than azithromycin monohydrate.” This amendment is made for purposes of clarification only and does not narrow the scope of the claim. In the Interference proceedings related to this application, the Director considered the meaning of “non-hygroscopic” as applied in the specification of U.S. Patent No. 6,365,574 (the parent patent of Reissue Application No. 10/816,376). In the November 8, 2006 Memorandum Opinion and Order, the Director stated “When [U.S. Patent No. 6,365,574] is considered as a whole, we find that “non-hygroscopic” means “less hygroscopic than azithromycin monohydrate.” (Page 42, lines. 10-11) (emphasis added). In light of the disclosures in the specification, it would be apparent to one skilled in the art that “non-hygroscopic” means “less hygroscopic than azithromycin monohydrate.”

The specification is also amended. The amendments to the specification are editorial and made only to correct errors in a chemical formula which would have been evident to a person skilled in the art. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

Status of the Patent Claims

Claim 1 is amended by deleting the term “non-hygroscopic” previously inserted into claim 1 of the patent, and by inserting “wherein the ethanolate is less hygroscopic than azithromycin monohydrate.”

Claims 2-5 have not been amended.

Claim 6 was previously amended by replacing “about 1.5% and about 2.5%” with “about 2.5% and about 3.5%.” Claim 6 is not further amended.

Claim 7 is also amended by deleting the term “non-hygroscopic” previously inserted into claim 7 of the patent, and by inserting “wherein the ethanolate is less hygroscopic than azithromycin monohydrate.”

Claims 8-15 of the patent were previously canceled.

Status of the Specification

The formula in the first paragraph following the subheading "Background of the Invention" was first amended in the February 3, 2005 Third Preliminary Amendment. The amendment was made to replace a carbon atom in the old structure with an oxygen atom adjacent to the carbonyl group, C=O. However, in addition to replacing the carbon atom with an oxygen atom, the Third Preliminary Amendment also inadvertently replaced the solid line connecting the CH₃ group at the ninth position with a dotted line. By the present amendment, the inadvertent error is corrected and the formula is amended only to include the oxygen atom. Applicants believe this amendment resolves any remaining issues regarding the form of amendments to the first paragraph following the subheading "Background of the Invention."

Applicants' Statement of Substance of Examiner Interview

The undersigned would like to thank Examiner Peselev for the courtesy extended in brief telephone interviews conducted on March 17 and 24, and June 23, 2009.

In the March 17 interview, the Examiner confirmed that the Office Action is non-final.

In the March 24 interview, the undersigned contacted the Examiner regarding clarification of the objections to the specification. The Examiner indicated that the objection was to the amendments to the specification made in the Applicant's February 2, 2005 Third Preliminary Amendment. The Examiner further indicated that while the amendments made in the February 2, 2005 Third Preliminary Amendment had been entered, the amendments were made in improper form. The Examiner requested that the Applicant resubmit the amendments in proper form. The Applicant raised the issue that because the Examiner had already entered the February 2, 2005 amendments, no further submission regarding this amendment was necessary. No agreement was reached. However, the Examiner agreed to withdraw the objection to the specification if the Applicant resubmitted the amendments in proper form.

In the June 23 interview, potential amendments to the claims were discussed to bring the application in condition for allowance. The Applicants' representatives proposed to the Examiner amending claims 1 and 7 to recite wherein the ethanolate is less hygroscopic than azithromycin monohydrate" instead of the term "non-hygroscopic" in order to clarify previously

recited claimed features and overcome the formal rejections of the Office Action. Upon an enquiry from the Examiner about the descriptive support for the claim amendments, the Applicants' representatives pointed out the location in the specification where the descriptive support could be found. The Examiner indicated that the amendments appeared to take care of the current rejections under 35 U.S.C. 112, but that further search and consideration of the relevant art would be required before allowing the application. Applicants note that in the Interview Summary, it appears that the Examiner intended to state the term "non-hygroscopic" instead of "non-hydroscopic" and to state "the 112 rejection" instead of "the 122 rejection."

Objection to the Specification

The Office Action objects to the specification allegedly because the amendment filed in the Applicant's February 2, 2005 Third Preliminary Amendment is in improper form. The amendment to the specification obviates this objection. Applicants believe that the amendments to the specification shown above correct any inadvertent errors in the chemical formula of azithromycin in the first paragraph of the Background of the Invention. Withdrawal of the objection is respectfully requested.

Objection to the Claims

The Office Action objects to the claims because the new claims inserted in the Applicant's February 2, 2005 Third Preliminary Amendment were not underlined. The Applicant contends that the objection is moot because the amendment filed on September 11, 2008 did not insert any new claims.

Reissue Oath/Declaration

The Office Action asserts that a supplemental reissue oath/declaration is required under 37 CFR 1.175(b)(1). The Applicant requests that the requirement of a supplemental reissue oath/declaration be held in abeyance until the claims are allowed.

Claim Rejection -- 35 U.S.C. 112, Second Paragraph

Claims 1-7 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office Action argues that "non-hygroscopic," as previously recited in claims 1

and 7, is not supported by the specification. Without conceding the propriety of this rejection, and solely to advance prosecution of this application, claims 1 and 7 are amended to recite, *inter alia*, “wherein the ethanolate is less hygroscopic than azithromycin monohydrate.” Applicants provide literal support for this feature at, for example, col. 1, ll. 61-63, of the specification. As such, Applicants respectfully submit that claims 1 and 7, and the claims depending therefrom, are definite.

Claim Rejection -- 35 U.S.C. 112, First Paragraph

Claims 1-7 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office Action asserts that the term “non-hygroscopic,” as previously recited in claims 1 and 7, lacks written description support in the specification. For at least the reasons discussed above with respect to the traversal of the §112, second paragraph, rejection, the Applicants respectfully submit that the feature of wherein the ethanolate is less hygroscopic than azithromycin monohydrate is supported by the specification.

Conclusion

Withdrawal of the objections and rejections is respectfully requested.

In the event that this Response is deemed not timely, applicants petition for an appropriate extension of time. The Commissioner is authorized to charge any required due fees, as related to this paper, to Deposit Account No. 11-0600.

Respectfully submitted,

Date: June 26, 2009

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